K031688

JUL 2 2003

## 1. 510(K) SUMMARY

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| **Submitter's Name:** | Guidant Corporation<br>CRM Division |
| **Submitter's Address:** | 4100 Hamline Avenue<br>Mail Stop F330<br>St. Paul, Minnesota 55112 |
| **Telephone:**<br>**Fax:** | (651) 582-4927<br>(651) 582-5134 |
| **Contact Person:** | Stephanie Isgrigg Robinson |
| **Date Prepared:** | May 30, 2003 |
| **Device Trade Name:** | Rotating Hemostasis Valve |
| **Device Common Name:** | Hemostasis Valve |
| **Device Classification Name:** | Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass, Hemostasis Valve |
| **Device Classification:** | Class II |

**Summary of Substantial Equivalence:**
The design, materials, method of delivery and intended use features of the modified Rotating Hemostasis Valve is substantially equivalent with regard to these features in their predicate device, Rotating Hemostasis Valve (K854261/12-04-85)

**Device Description:**
The RAPIDO™ Cut-Away Rotating Hemostasis Valve is recommended for use during vascular procedures in conjunction with interventional and/or diagnostic devices such as balloon catheters, wires, and pacemaker and defibrillation leads. The RAPIDO™ Cut-Away Rotating Hemostasis Valve has a single adjustable seal that provides control over fluid loss.

The seal is a Tuohy-Borst type that may be adjusted by rotating the cap clockwise to close, and counterclockwise to open. The seal is adjusted to control leakage and device movement. An open RHV seal allows air and fluid to be purged while allowing the advancement/withdrawal of diagnostic/ interventional devices

**Intended Use:**
The Guidant Hemostasis Valve is used to maintain hemostasis around catheters percutaneously introduced into the vasculature.

**Technological Characteristics:**
Comparisons of the proposed and predicate device show that the technological characteristics such as materials, performance characteristics, sterilization and packaging are identical or substantially equivalent to the currently marketed predicate device.

**Performance Data:**
The results of the verification testing demonstrate that the modified Rotating Hemostasis Valve meets the established acceptance criteria and perform in a manner equivalent to the predicate device. No new safety or effectiveness issues were raised during the testing program.

**Conclusions:**
The modified Rotating Hemostasis Valve has the same intended use, technological characteristics, and performance properties as the Guidant approved Rotating Hemostasis Valve. Therefore, there are no new safety or effectiveness issues. The modified Rotating Hemostasis Valve is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 2003

Guidant Corporation
c/o Ms. Stephanie Isgrigg Robinson
4100 Hamline Avenue North
St. Paul, MN 55112-5798

Re: K031688
RAPIDO™ Cut-Away™ Rotating Hemostasis Valve
Regulation Number: 870.4290
Regulation Name: Cardiopulmonary Bypass Adaptor, Stopcock, Manifold, or Fitting
Regulatory Class: Class II (two)
Product Code: 74 DTL
Dated: May 30, 2003
Received: June 2, 2003

Dear Ms. Robinson:

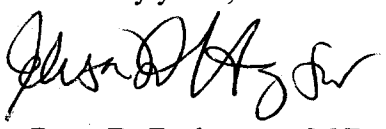
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## INDICATIONS FOR USE STATEMENT

**510(k) Number** K031688

**Device Name** RAPIDO™ Cut-Away™ Rotating Hemostasis Valve

**Indications for Use** The Rotating Hemostasis Valve is intended for maintaining a fluid- tight seal around devices, including implantable coronary venous leads, during the implant procedure.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Prescription Use Only

for BPZ

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